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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,118	09/29/2005	Karl Lintner	SEDERM 3.3-009	9458
	7590 11/04/200 /ID, LITTENBERG,	9	EXAMINER	
KRUMHOLZ &	& MENTLIK		GULLEDGE, BRIAN M	
600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			ART UNIT	PAPER NUMBER
,			1612	
			MAIL DATE	DELIVERY MODE
			11/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/519,118	LINTNER, KARL			
Office Action Summary	Examiner	Art Unit			
	Brian Gulledge	1612			
The MAILING DATE of this communication app	pears on the cover sheet with the c	orrespondence address			
Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period value to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin vill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on <u>27 August 2009</u> .  2a) This action is <b>FINAL</b> .  2b) This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
closed in accordance with the practice under L	.x pane Quayle, 1955 C.D. 11, 40	0.0.210.			
Disposition of Claims					
<ul> <li>4) ☐ Claim(s) 18-22 and 24-43 is/are pending in the 4a) Of the above claim(s) 22,24,30-37,40,42 ar</li> <li>5) ☐ Claim(s) is/are allowed.</li> <li>6) ☐ Claim(s) 18-21,25-29,38,39 and 41 is/are rejection.</li> <li>7) ☐ Claim(s) is/are objected to.</li> <li>8) ☐ Claim(s) are subject to restriction and/or</li> </ul>	nd 43 is/are withdrawn from consi	deration.			
Application Papers					
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correct and the correct of the contract	epted or b) objected to by the Idrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list	s have been received. s have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage			
Attachment(s)					
1) Notice of References Cited (PTO-892)	4) Interview Summary				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:				

### **DETAILED ACTION**

### Previous Rejections

Applicants' arguments, filed August 27, 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

# Claim Rejections - 35 USC § 112, New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-21, 25-29, 39, and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This is a "new matter" rejection. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 18 has been amended to recite that the cosmetic composition "consists essentially of" the subsequently recited ingredients. There is insufficient support for this limitation in the originally filed disclosure. The disclosure does not define or discuss any compositions as "consisting essentially of" any ingredients, does not define as "essential" any ingredients, and does not provide a clear

Art Unit: 1619

indication what the basic and novel characteristics actually are for the claimed invention. As such, the amendment is not supported by the originally filed disclosure.

Page 3

## Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18-21, 25-29, 38-39, and 41 stand rejected under 35 U.S.C. 102(b) as being anticipated by Satoh et al. (European Patent Application 0189861). The Applicant argues that the rejection of the claims is not proper, as the claims now recite that the cosmetic consists essentially of the subsequently recited ingredients, and as such the combination of ingredients present in the embodiment disclosed by Satoh et al. is excluded by the claim language. The Applicant also argues that the rejection of claim 38 is not proper, as the claim recites a product and limitations directed to how the material was prepared. Applicant states that a recent court ruling (Abbott Labs. v. Sandoz, Inc.) decided that for infringement purposes that "process terms in product-by-process claims serve as limitations in determining infringement." Applicant further argues that it is "unreasonable to have claims interpreted in different ways – one way for infringement and one way for patentability." The Applicant further argues that the rejection is not proper as the dependent claim 39 requires an additional ingredient which reduces melanin.

The Examiner is not persuaded by these arguments. While claim 18 has been amended to recite that the composition consists essentially of an excipient and a compound of formula I, the specification does not provide a clear indication what the basic and novel characteristics actually are for the claimed invention, and as such the transitional phrase "consisting essentially of" will

be construed as equivalent to "comprising." See MPEP 2111.03. And Satoh et al. discloses a composition comprising an excipient and a compound of formula I. The Examiner also notes the court case cited relates to infringement, and not to prosecution of an application and the examination of claims. The MPEP still discusses product-by-process limitations, and how these limitations are to be examined (MPEP 2112), and until the MPEP is revised, an infringement ruling will not be relied upon to go against the practices set forth in the MPEP. Finally, the Examiner doe snot find that claim 39 recites an additional ingredient, the ingredient having the property of reducing melanin, but rather the claim recites the further limitation that an ingredient present has this property, which octopamine inherently possesses.

#### Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1619

however, will the statutory period for reply expire later than SIX MONTHS from the date of this

final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Brian Gulledge whose telephone number is (571) 270-5756. The

examiner can normally be reached on Monday-Thursday 6:00am - 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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**BMG** 

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612